

Accompanying this Amendment is a petition for a three month extension of time Pursuant to 37 CFR 1.136 including an authorization for the Commissioner to charge Deposit Account No. 04-1529 the fees due under 37 C.F.R. §§1.16 and 1.17.

Response

Rejection of Claims 1-13 under 35 U.S.C. §112, First Paragraph.

Claims 1-13 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while clearly enabling DNA coding for one single chain antibody (SCAb-TP1) that specifically binds to the Δ -9 desaturase transit peptide, fails to enable the full scope of claims. Applicants respectfully traverse.

The Examiner carefully explained that the specification does not provide any specific guidance for identifying other anti-transit peptide antibodies whose *in planta* expression would result in a decreased steady state level of the cognate passenger protein. It was also noted that the specification failed provide any structural or physical characteristics of anti-transit peptide antibodies that correlate with decreasing steady state levels of a cognate passenger protein.

Applicants have amended the scope of their claims relating to what transit peptides the anti-transit peptide antibody must bind. The amendment, while not narrowing the Claims to what the Examiner states the specification clearly enables, does vastly limit the scope of claims commensurate in scope to what the specification reasonably enables.

Original Claim 1 circumscribed the anti-transit peptide antibodies in a purely function manner by reciting that the antibodies should bind to any transit peptide that “directs a passenger protein associated with the transit peptide to an organelle of a plant cell.” This functional definition of the antibody’s target antigens, coupled with the

statement in the specification starting on page 11, line 34, discussing the lack of sequence homology and varying lengths of plant transit peptides, no doubt troubled the Examiner. Applicants understand the Examiner's concern and realize the immense number of antibody targets, transit peptides, the functional language encompassed.

The amendment limits the scope of Claim 1 by replacing the phrase "that directs a passenger protein associated with the transit peptide to an organelle of a plant cell" with the phrase "selected from the group consisting of SEQ ID NO:15 and SEQ ID NO:56." Basis for this amendment is found in the specification on page 50, lines 5-8, and on page 71, lines 21-28, as well as in the sequence listings. Thus the amendment serves to reduce the previously massive number of anti-transit peptide antibodies to the rather limited group of antibodies that bind either SEQ ID NO:15 (maize stearyl-ACP Δ -9 desaturase) or SEQ ID NO:56 (maize palmitoyl-ACP thioesterase).

Applicants believe they have fully addressed the basis of the Examiner's rejection and assert the amendment to Claim 1, from which all the pending claims depend, overcomes the present rejection. Therefore, Applicants respectfully request the Examiner to remove the rejection of Claims 1-13 under 35 U.S.C. §112.

Rejection of Claims 1-13 Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected Claims 1-13 under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. The Claims were rejected for a variety of reasons that will be addressed below point by point. Most of the rejections related to formalistic claim language dealing with antecedent basis or grammar. Applicants appreciate the Examiner's careful attention to such detail and wish to thank her for pointing them out

and kindly offering alternate acceptable language. Other rejections dealt with clarity issues that will be addressed below either through amendment or by way of explanation.

Claim 1 was deemed indefinite based on the recitation of “associated” in the second element. The amendment to Claim 1 discussed above removed this word and also rendered this portion the present rejection moot.

Claim 1 was rejected as indefinite for reciting “having the ability to bind a transit peptide” because the Examiner felt it was not clear whether the quoted limitation applied to “an antibody”, to “fragment thereof”, or to both. Applicants wish to draw the Examiner’s attention to the definition of “antibody” found on the paragraph bridging pages 4 and 5 of the specification. The last sentence of the definition states that the term “antibody” includes immuno-reactive fragments, segments etc. Based on this definition and guidance found throughout the specification relating to this point, Applicants have clearly intended the terms “antibody” and “fragment thereof” to be generally allied. Therefore the phrase “having the ability to bind a transit peptide” applies to both “antibody” and “fragment thereof”.

Claim 1 was further rejected because it was unclear what “directs a passenger protein”. Again, based on the amendment to Claim 1 made to address the enablement rejection, this portion of the present rejection is rendered moot because the language in question, “directs a passenger protein”, was removed by amendment.

Claims 1 and 10 were deemed indefinite by the use of the term “fragment thereof” because the Examiner felt it was not clear what type of antibody fragments were encompassed. Applicants note the definition of “antibody” cited above explains that only immunologically-active fragments are included. Moreover the specification discusses antibody fragments in greater detail on page 21 and sheds considerable light on the Examiner’s concern. Based on the cited passages and the mature state of the field of

humoral immunology, Applicants assert the ordinarily skilled immunologist will readily understand what is meant by an immunologically-active antibody fragment.

Claims 2, 3, and 4 were all rejected because the indefinite article “a” was used when antecedent basis had already been established for the noun it introduced. The Examiner correctly noted “the” should have been used instead. Applicants apologize for this error and have amended Claims 2, 3, and 4 according to the Examiner’s guidance.

Claims 3 and 4 were rejected because of improper grammar in that the nouns “dicotyledon” and “monocotyledon” were used to modify the noun “cell”. Applicants wish to thank the Examiner for pointing out this obvious error and have made the amendment offered by the Examiner to overcome the rejection.

Claims 5 and 13 were deemed indefinite in the recitation of “derived” because it was not clear to the Examiner what was being retained in the derived product. Claim 5, which depends from Claim 2, in essence claims a plant cell transformed by the nucleic acid construct of Claim 1. Thus the derived plant or progeny in Claim 5 refers to a plant regenerated from the transformed cell, or to plants bred with the transformed plant, both of which must possess the recombinant phenotype (e.g. expression of the anti-transit peptide antibody) to fall within the Claim 5. Similarly, Claim 13 is meant to claim a plant regenerated from the cell of Claim 12, or plants bred from such plants, which retain the recombinant phenotype. Applicants believe this also explains that both the plant and the progeny in Claim 5 ultimately stem from the plant cell of Claim 2 by virtue of the fact that they must possess the recombinant phenotype.

Claim 6 was found indefinite for reciting “a maize plant of Claim 5” because there was insufficient antecedent basis for “maize”. Applicants have made the amendment recommended by the Examiner to overcome this rejection.

Claim 7 was deemed indefinite for improperly using the indefinite article “a” in front of “maize plant”. The Claim was amended to recite “the maize plant” as suggested by the Examiner.

Claim 10 was found indefinite for reciting “is a single chain antibody molecule” because it was not clear to the Examiner whether the phrase applied to “said antibody”, to “fragment thereof”, or to both. The explanation here is similar to what was explained in the rejection to Claims 1 and 10 on page 5 of this amendment. The phrase “is a single chain antibody” applies to both “said antibody” and to “fragment thereof” because it implicitly means that the immuno-reactive portion of “said antibody” or “fragment thereof” is used to construct a single chain antibody which Applicants assert the ordinarily skilled immunologist with readily understand.

Claim 11 was rejected for reciting “said epitope” because there was no antecedent basis. Applicants apologize for this careless error and have deleted entire Claim 11 to overcome this portion of the rejection.

Claim 8 was rejected as indefinite as being incomplete for omitting essential steps, namely the nucleic acid expression step. Applicants have added the phrase “and expressing said construct thereby producing an immunologically functional antibody or fragment thereof” to the end of Claim 8. Basis for the amendment is found generally in Examples 11 and 12. Applicants assert the amendment adds the missing step noted by the Examiner.

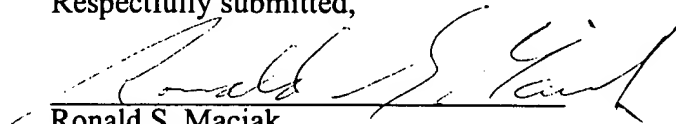
Summary

An amendment was made to Claim 1 to overcome the rejection based on 35 U.S.C. §112, first paragraph. Amendments also were made to Claims 1-4 and 6-8 to

address the rejections under 35 U.S.C. §112, second paragraph, along with explanations of some allegedly unclear claim language.

In view of the foregoing, Applicants contend they have fully responded to, and overcome, all of the pending rejections and believe the case will be in condition for allowance upon entry of this Amendment. Therefore, Applicants respectfully request the Examiner to enter the amendment, favorably consider the subject application and pass it to issuance in due course.

Respectfully submitted,



Ronald S. Maciak
Attorney for Applicants
Registration No. 35,262
Phone: (317) 337-4829

Dow AgroSciences LLC
Patent Section
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

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Complete Marked-up Claim Set

1. A nucleic acid construct comprising in the 5' to 3' direction of transcription,
a promoter functional in a plant cell,
a nucleic acid sequence that encodes an antibody or fragment thereof having the ability to bind to a transit peptide selected from the group consisting of SEQ ID NO:15 and SEQ ID NO: 56 [that directs a passenger protein associated with the transit peptide to an organelle of a plant cell], and
a termination region functional in a plant cell.
2. A plant cell comprising the [a] nucleic acid construct according to Claim 1.
3. The [A] plant cell of Claim 2, wherein said plant cell is from a dicotyledonous plant. [that is a dicotyledon.]
4. The [A] plant cell of Claim 2, wherein said plant cell is from a monocotyledonous plant. [that is a monocotyledon.]
5. A plant or progeny thereof derived from the plant cell of claim 2.
6. The [A maize] plant of claim 5, wherein said plant is a maize plant.
7. The [A] maize plant of claim 6 wherein said transit peptide is selected from the group consisting of SEQ ID NO:15 and SEQ ID NO: 56. [the transit peptide for maize stearoyl-ACP Δ -9 desaturase or maize palmitoyl-ACP thioesterase.]
8. A method of decreasing the steady state level of a passenger protein in a plant cell which comprises placing a nucleic acid construct of claim 1 in the plant cell and expressing said construct thereby producing an immunologically functional antibody or fragment thereof.
9. The method of Claim 8 wherein said organelle is selected from the group consisting of chloroplast, amyloplast, chromoplast, leucoplast, mitochondria, and the nucleus.

10. The method of Claim 8 wherein said antibody or fragment thereof is a single chain antibody molecule.
- [11. The method of Claim 8 wherein said epitope comprises at least 6 amino acids, said amino acids being continuously adjacent to each other in said transit peptide.]
12. A plant cell wherein the steady state level of a passenger protein found therein has been decreased by the method of Claim 8.
13. A plant or progeny thereof derived from a plant cell of claim 12.